REMARKS

In the Office Action dated August 7, 2000, the Examiner has acknowledged Applicants' provisional election of claims 1-8 and 14-17 made in the response filed June 21, 2000. However, the Examiner has set forth a further requirement for restriction under 35 U.S.C. §121 as follows:

> Groups I-VII. Claims 1-8 and 14-17, drawn to an isolated nucleic acid molecule, classified in class 536, subclass 23.5.

The Examiner has alleged that Groups I-VII are independent and distinct, because they are products which possess characteristic differences in the structure and function, and each product has an independent and distinct utility. The Examiner states that the nucleic acid molecules, SEQ ID NOS: 1, 4, 5, 7, 9, 11 and 13 each encode a different opioid receptor. Thus, the Examiner considers that a requirement for restriction is proper.

A telephone interview was conducted on September 6, 2000 to clarify the meaning of the foregoing restriction. Applicants wish to thank the Examiner for the courtesy extended on behalf of Applicants during the telephone interview. It is Applicants' understanding that Examiner contends that the previously elected Group I, claims 1-8 ad 14-17 read on multiple nucleic acid molecules, SEQ ID NOS: 1, 4, 5, 7, 9, 11 and 13. It is the Examiner's opinion that these nucleic acid molecules are independent and distinct each from the other. The Examiner requires Applicants to make a further election from these nucleic acid molecules. However, as a result of the discussion during the telephone interview, the Examiner indicated to the undersigned that he would be willing to examine SEQ ID NOs: 4-5, 7, 9, 11 and 13 together.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect SEQ ID NO: 5 for further prosecution. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application. However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

> An Examiner's authority to require restriction is defined and limited by statute:
> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. §121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized.

In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement. In particular, the nucleic acid molecules, SEQ ID NOS: 1, 4, 5, 7, 9, 11 and 13 are related to each other. These nucleic acid molecules all encode an OGF receptor, i.e., they are functionally related. These nucleic acid molecules are also structurally related. More specifically, as described in the present specification, at page 12, lines 15-26, SEQ ID NOs: 4-5, 7, 9, 11 and 13 encode alternatively spliced forms of a human OGF receptor and share a portion of the nucleotide sequence at the 5' region, but differ in the 3' region. See, also, Figure 8. In addition, SEQ ID NOS: 1 and 3 encode a rat OGF receptor which shares a high degree of homology to human OGF receptor. See, page 19, line 25 to page 20, line 5. Thus, it is respectfully submitted that SEQ ID NOS: 1, 3, 4-5, 7, 9, 11 and 13 are functionally and structurally related to one another – they are not distinct and independent molecules.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

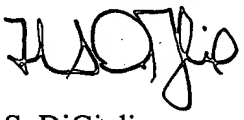
Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction, or at least include SEQ ID NO: 4-5, 7, 9, 11 and 13 (all encoding a human OGF receptor) in the examination.

Respectfully submitted,



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